Supreme Court, U.S.
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No. 01-344

In The

Supreme Court of the United States

TOMMY G. THOMPSON,
Secretary of Health and Human Services, et al.,

Petitioners,

v.

WESTERN STATES MEDICAL CENTER, et al.,

Respondents.

On Writ Of Certiorari
To The United States Court Of Appeals
For The Ninth Circuit

BRIEF OF RESPONDENTS

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QUESTION PRESENTED FOR REVIEW

Whether the advertisement, promotion, and solicitation restrictions contained in the Food and Drug Administration Modernization Act of 1997 violate the First Amendment.

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT PURSUANT TO RULE 29.6

The Respondents are: Western States Medical Center Pharmacy, a Nevada corporation*; Women's International Pharmacy, a Wisconsin corporation; Health Pharmacy, a Wisconsin corporation; College Pharmacy, a Colorado corporation; Wedgewood Village Pharmacy, a New Jersey corporation; ApotheCure, a Texas corporation; and Lakeside Pharmacy, a Tennessee corporation.

None of the Respondents has a parent corporation. None of the Respondents has stockholders that are publicly held companies owning 10% or more of the stock in the corporation.

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* TKG California Inc. d/b/a Kronos Pharmacy purchased the assets of Western States Medical Center Pharmacy. TKG California Inc. d/b/a Kronos Pharmacy is not a party hereto but has an interest in the proceedings. TKG California Inc. d/b/a Kronos Pharmacy and its parent, The Kronos Group, Inc., and its parent, Exeter Life Sciences, Inc., are not publicly held companies.

TABLE OF CONTENTS

Page

QUESTION PRESENTED FOR REVIEW i

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT PURSUANT TO RULE 29.6 ii

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES vi

STATEMENT OF THE CASE 1

A. Introduction 1

B. Statement of Facts 2

C. 21 U.S.C. Section 353a, State Laws, and the Absence of Restrictions on Compounding 5

SUMMARY OF ARGUMENT 12

ARGUMENT 15

I. THE COURTS BELOW CORRECTLY HELD THAT THE RESTRICTIONS ON TRUTHFUL AND NON-MISLEADING ADVERTISEMENT AND SOLICITATION CONTAINED IN SECTIONS 353a(a) AND (c) VIOLATE THE FIRST AMENDMENT 15

A. Petitioners Have The Burden Of Satisfying The *Central Hudson* Criteria 15

B. Petitioners Have Not Shown That They Have A Substantial Interest 18

C. Petitioners Have Not Shown That The Restrictions On Respondents' Truthful And Non-Misleading Advertising And Soliciting Materially Advance Petitioners' Asserted Interests 23

TABLE OF CONTENTS – Continued

Page

1. FDA's prior enforcement actions are irrelevant to the unconstitutionality of the challenged restrictions but do reveal that the FDA did not consider "compounding" to be "manufacturing" 23

2. The power to regulate compounding, a commercial activity, does not include the power to restrict advertising, promoting and solicitating 25

3. Patient need and physician judgment drive demand for compounds, not advertisement, promotion, and solicitation 28

4. Petitioners have not demonstrated that the challenged speech restrictions will materially prevent a circumvention of the drug approval process 29

5. FDAMA is so riddled with exceptions that it cannot directly and materially advance Petitioners' asserted interest 30

D. Section 353a Does Not Accomplish The Asserted Ends In A Manner That Is No More Extensive Than Necessary 32

II. PHARMACY COMPOUNDED DRUGS ARE NOT NEW DRUGS 34

A. The Inapplicability Of 21 U.S.C. § 321(p)(1) And The Impossibility Of Clinical Trials For Compounds 35

B. The Effects Of 21 U.S.C. §§ 360(a)(1), 360(g)(1), And 374(a)(2)(A) 37

C. Petitioners' Cases Do Not Apply 40

TABLE OF CONTENTS – Continued

Page

D. The FDA's Historical Hands-Off Approach To Pharmacy Compounding 42

E. Adequacy Of Existing Regulations And Patient Protection 44

III. PETITIONERS CANNOT CONDITION EXEMPTION FROM THE FDA'S NEW DRUG APPROVAL PROCESS ON RELINQUISHMENT OF FIRST AMENDMENT RIGHTS 45

CONCLUSION 48

TABLE OF AUTHORITIES

Page

CASES

Bates v. State Bar of Arizona, 433 U.S. 350 (1977) 26

Burson v. Freeman, 504 U.S. 191 (1992) 17, 18

Carey v. Population Serv. Int'l, 431 U.S. 678 (1977) 26

Cedars North Towers Pharmacy, Inc. v. United States, [1978-1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,200 (S.D. Fla. Aug. 28, 1978) 40

Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980) 12, 15, 16, 20, 32

Dolan v. City of Tigard, 512 U.S. 374 (1994) 45, 47

Edenfield v. Fane, 507 U.S. 761 (1993) 16, 17

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) 24, 35, 39

Florida Bar v. Went For It, Inc., 515 U.S. 618 (1995) .. 17, 18

44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996) ..... *passim*

Greater New Orleans Broad. Ass'n v. United States, 527 U.S. 173 (1999) 26, 29, 30

Ibanez v. Florida Dep't of Bus. & Prof'l Regulation, 512 U.S. 136 (1994) 16, 17, 30

Keyinshan v. Board of Regents, 385 U.S. 589 (1967) 48

Lorillard Tobacco Co. v. Reilly, 121 S. Ct. 2404 (2001) 17, 18, 34, 46

Munro v. Socialist Workers Party, 479 U.S. 189 (1986) 18

TABLE OF AUTHORITIES – Continued

Page

Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) 24, 27, 28

Pharmanex v. Shalala, 221 F.3d 1151 (10th Cir. 2000) 42

Pickering v. Board of Educ., 391 U.S. 563 (1968) 45, 47

Posadas de Puerto Rico Associates v. Tourism Co. of P.R., 478 U.S. 328 (1986) 46

Professionals & Patients for Customized Care v. Shalala, 56 F.3d 592 (5th Cir. 1995) 24, 41

Professionals & Patients for Customized Care v. Shalala, 847 F. Supp. 1359 (S.D. Tex. 1994) 24

Rubin v. Coors Brewing Co., 514 U.S. 476 (1995) 26, 31, 32, 33

United States v. 9/1 KG. Container, 854 F.2d 173 (7th Cir. 1988) 36, 42

United States v. Ortiz, 422 U.S. 891 (1975) 34, 46

United States v. Rutherford, 442 U.S. 544 (1979) 37, 43

United States v. Sene X Eleemosynary Corp., Inc., 479 F. Supp. 970 (S.D. Fla. 1979), *aff'd*, [1982-1983 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,207 (11th Cir. 1983) 30, 41

United States v. United Foods, Inc., 121 S. Ct. 2334 (2001) 34, 46

USV Pharm. Corp. v. Weinberger, 412 U.S. 655 (1973) 42

Valley Broad. Co. v. United States, 107 F.3d 1328 (9th Cir. 1997) 26

Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976) 26, 33

TABLE OF AUTHORITIES – Continued

Page

Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998) 24, 44

Washington Legal Found. v. Friedman, 36 F. Supp. 2d 16 (D.D.C. 1999) 24

Washington Legal Found. v. Henney, 56 F. Supp. 2d 81 (D.D.C. 1999), *vacated at* 202 F.3d 331 (D.C. Cir. 2000) 25

Weinberger v. Bentex Pharm., Inc., 412 U.S. 645 (1973) 29, 37, 39, 42

Weinberger v. Hynson, Wescott & Dunning, Inc., 412 U.S. 609 (1973) 30, 35, 36, 37

Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985) 16, 17, 30

CONSTITUTION, STATUTES AND REGULATIONS

U.S. Const. Amend. I ..... *passim*

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

21 U.S.C. § 321(p)(1) (1994) 4, 23, 34, 35, 36, 37

21 U.S.C. § 351(a)(2)(B) (Supp. V 1999) 5, 6

21 U.S.C. § 352(f)(1) (1994 & Supp. V 1999) 5, 6

21 U.S.C. § 353a (Supp. V 1999) ..... *passim*

21 U.S.C. § 353a(a) (Supp. V 1999) ..... *passim*

21 U.S.C. § 353a(a)(1) (Supp. V 1999) 5

21 U.S.C. § 353a(b) (Supp. V 1999) 6

21 U.S.C. § 353a(b)(1)(C) (Supp. V 1999) 6

TABLE OF AUTHORITIES – Continued

Page

21 U.S.C. § 353a(b)(3)(B) (1994 & Supp. V 1999) ..7, 31

21 U.S.C. § 353a(b)(3)(B)(i) (Supp. V 1999) 7

21 U.S.C. § 353a(b)(3)(B)(ii) (Supp. V 1999) 7

21 U.S.C. § 353a(c) (Supp. V 1999) ..... *passim*

21 U.S.C. § 355 (1994 & Supp. V 1999) 5, 6

21 U.S.C. § 360(a)(1) (1994) 8, 13, 37, 38, 40

21 U.S.C. § 360(g)(1) (1994) ..... *passim*

21 U.S.C. § 360(g)(2) (1994) 42

21 U.S.C. § 374(a)(2)(A) (1994) ..... *passim*

Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (21 U.S.C. 353a (Supp. V 1999) ..... *passim*

Wis. Stat. Ann. § 450.01(3) 12, 20

Wis. Stat. Ann. § 450.01(7) 20, 38

Wis. Stat. Ann. § 450.01(13) 20

MISCELLANEOUS

Compliance Policy Guide 7132.16 1

Sen. Rep. No. 105-43 (1997) 3

143 Cong. Rec. S 9811-04 (daily ed. Sept. 24, 1997) ..4, 23

STATEMENT OF THE CASE

A. Introduction

Petitioners' brief raises issues unrelated to the First Amendment and underscores what this case is not about. It is not about dispensing unsafe, ineffective or "unreasonable" quantities of compounded drugs, false or misleading advertisement, or illegal activity. This case is about absolute restrictions on truthful, non-misleading advertisement and solicitation contained in the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), at 21 U.S.C. §§ 353a(a) and (c) (Supp. V 1999), that violate the First Amendment.

This case is before the Court after rulings on cross-motions for summary judgment in the district court and affirmed (in part) by the Ninth Circuit. Petitioners offered no evidence establishing that the distribution of compounded drugs poses a health risk or that Respondents' advertising creates demand for compounds. There is no evidence that Respondents ever practiced pharmacy other than in the regular course and in conformity with federal and State laws. Petitioners' sole "evidence" that the dispensing of compounded prescription drugs caused any alleged health risk was their reference to a double hearsay anecdote in their own Compliance Policy Guide 7132.16 ("CPG"). (Pets.' App. 73a.)[1] Petitioners now attempt to shore-up their barren record with hearsay from websites (Pets.' Br. 27, 34) and journal articles (Pets.'

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[1] Cites to the appendix attached to Petitioners' petition for *certiorari* are designated "Pets.' App. ___," cites to Petitioners' brief are designated "Pets.' Br. ___."

Br. 28, 35) never presented below, the admissibility of which has never been tested under the rules of evidence.

B. Statement of Facts

Respondents are seven licensed pharmacies, located in seven states, specializing in working with physicians to compound drugs for individual patient needs. Respondents advertise, promote and educate physicians and patients about the availability of particular compounded drugs, classes of drugs, and types of drugs. (Verified Compl., ¶ 27; Grp. Exh. 2 to Verified Compl.)

Compounding is the process whereby a pharmacist, pursuant to a physician's prescription, combines, mixes, or alters ingredients to create a customized medication for a patient for whom a manufactured drug is unavailable. The tripartite relationship under which this occurs, *i.e.*, the interplay between physician, patient and pharmacist, is referred to as the "triad." (Verified Compl., ¶ 29.) This triad is in contrast to manufacturers who have no relationship with either physician or patient, but manufacture for distribution to wholesalers and distributors, do not customize for a patient's unique medical needs, and receive no physician prescriptions. Compounded drugs are prescribed by physicians to address many medical problems including cancer, infertility, PMS, menopause, and pain. Pharmacy compounding is a customary and required part of pharmacy practice, a mandatory subject in most pharmacy schools, and most, if not all, State laws require that pharmacists be proficient in compounding and maintain compounding equipment in their pharmacies. (Verified Compl., ¶¶ 19, 20, 31.)

Pharmacists compound a drug product when: manufactured drugs are unavailable; there is no commercially available product to accomplish a desired medical objective (Verified Compl., ¶ 21(a)); a patient is allergic to a manufactured ingredient (Verified Compl., ¶ 21(b)); a manufactured drug is unavailable in an appropriate dose (Verified Compl., ¶ 21(c)); there is a need for carefully calibrated hormone treatments for infertility, cancer, *etc.* (Verified Compl., ¶ 21(d)); and the patient requires an alternative delivery system, *e.g.*, injection, dermal patch, suppository, *etc.* (Verified Compl., ¶ 21(e).) Compounding pharmacists do not compete with drug manufacturers but provide drugs in the interstitial spaces where a manufactured drug does not exist or is unsuitable.

Because of the specialization among and co-dependence between compounding pharmacists and physicians, it is vital that they establish contact and dialogue. This is accomplished by Respondents' advertisement and solicitation, including presentations at medical conventions. (Verified Compl., ¶¶ 28, 30.) Frequently, but for the pharmacist's consultation, neither physician nor patient would be aware of the availability of dosages, drug delivery systems, or the ability to compound certain particular drugs. (Verified Compl., ¶ 23.) This consultation is a vital component of the pharmacist's role as a professional. (Verified Compl., ¶ 4.)

Compounding is not illegal under State or federal law. "[A]ll States include compounding as a core component of the profession of pharmacy." Sen. Rep. No. 105-43, at 67 (1997). Before FDAMA (and to this day), pharmacy practice and its component, compounding,

have been regulated by State law. By contrast, drug manufacturing has been regulated by federal and State law. *See, e.g.*, 143 Cong. Rec. S 9811-04 at S 9839 (daily ed. Sept. 24, 1997). The Food Drug and Cosmetic Act ("FDCA") specifically exempts pharmacies:

> . . . which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy . . . which are regularly engaged in dispensing prescription drugs . . . upon prescriptions of practitioners licensed to administer such drugs . . . to patients under the care of such practitioners in the course of their professional practice and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

21 U.S.C. § 374(a)(2)(A) (1994). *See also* 21 U.S.C. § 360(g)(1) (1994). Notwithstanding Petitioners' argument to the contrary, compounds are not mentioned or included in the FDCA's definition of "new drug" at 21 U.S.C. § 321(p)(1) (1994).

Prescriptions for compounded drugs, depending on the Respondent, constitute between 60% and 90% of their total prescription orders. (Verified Compl., ¶ 26; *see also*, Pets.' App. 61a.) The volume of compounded drugs dispensed is determined by physicians evaluating patients' needs. It is not increased by Respondents' advertising beyond pre-existing patient need.

C. 21 U.S.C. Section 353a, State Laws, and the Absence of Restrictions on Compounding

In 1997, Congress enacted § 127 of FDAMA, Pub. L. No. 105-115, 111 Stat. 2296 (21 U.S.C. § 353a (Supp. V 1999)), which amended the FDCA by adding § 503(a), codified at 21 U.S.C. § 353a ("Section 353a"). Section 353a addressed compounded drugs and provided that §§ 351(a)(2)(B), 352(f)(1) and 355[2] of the FDCA shall not apply to a drug product as long as:

- No one compounds a drug product who is not a licensed pharmacist or physician. 21 U.S.C. § 353a(a)(1) (Supp. V 1999).
- No licensed pharmacist or physician dispenses a compounded drug unless it is in response to a prescription order for an individual patient or is based upon a history of such valid prescription orders. 21 U.S.C. § 353a(a) (Supp. V 1999).
- A pharmacist or physician only compounds a drug product from a bulk substance that complies with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, but if such a monograph does not exist, then from a list approved or developed by the Secretary of the United States Department of Health and

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[2] Section 351(a)(2)(B) established requirements for good manufacturing practices. 21 U.S.C. § 351(a)(2)(B) (Supp. V 1999). Section 352(f)(1) established the requirements for the labeling of approved drugs, including directions for use. 21 U.S.C. § 352(f)(1) (1994 & Supp. V 1999). Section 355 establishes the requirements for approval of new drugs. 21 U.S.C. § 355 (1994 & Supp. V 1999).

Human Services. 21 U.S.C. § 353a(b) (Supp. V 1999).

- No physician or pharmacist compounds a drug that has been withdrawn or removed from the market and which appears on a list published by the Secretary of the United States Department of Health and Human Services. 21 U.S.C. § 353a(b)(1)(C) (Supp. V 1999).[3]

Additionally, §§ 353a(a) and (c) required that Respondents not engage in advertising and soliciting. Section 353a(a) provided in pertinent part:

> Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order. . . .

21 U.S.C. § 353a(a). Section 353a(c) provided:

> (c) Advertising and Promotion. A drug may be compounded under subsection (a) of this section only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may

[3] Because Respondents believed that these provisions were desirable and severable from the speech restrictions contained in §§ 353a(a) and (c), Respondents argued below that if those speech restrictions were found to be unconstitutional, the court should sever and uphold the non-speech restrictions. The Ninth Circuit rejected Respondents' argument, reversed the district court on this point, and invalidated FDAMA in its entirety. (Pets.' App. 57a-59a.)

> advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

21 U.S.C. § 353a(c).

Section 353a also provided for a Memorandum of Understanding ("MOU") between the Food and Drug Administration ("FDA") and the States. 21 U.S.C. §§ 353a(b)(3)(B)(i) and (ii) (Supp. V 1999). MOUs were to provide that a compounding pharmacy dispensing interstate is subject to investigation and enforcement by both the State in which the dispensing pharmacy is located and the patient's State. Prior to the enactment of § 353a(b)(3)(B), there were no restrictions on the amount of compounded drugs that a pharmacy could dispense interstate. In response to this lawsuit, Petitioners agreed not to enforce the 5% and companion 19.9% MOU limitations. (Defs. Opp'n to Pls.' Mot. T.R.O., at 9.) Therefore, there has never been a volume limitation under either State or federal law on either interstate or intrastate dispensing of compounded drugs. Even if the percentage limitations had been enforced, realistically there would have been no ban on interstate dispensing of compounds because 20 pharmacies or a chain pharmacy could fill the out-of-state demand, thereby legally nullifying any restriction on interstate dispensing. The only activity restricted by FDAMA was the advertisement, promotion, and solicitation of the compounding of any particular drug, class of drugs, or type of drugs, *i.e.*, speech not conduct.

The fundamental and express differences between manufacturing and compounding are set forth in State pharmacy laws and the FDCA, *i.e.*, 21 U.S.C. §§ 360(a)(1) (1994), 360(g)(1) (1994), and 374(a)(2)(A) (1994). For example, under § 360(a)(1), pharmacy compounding is specifically excluded as it refers to drugs distributed " . . . from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer. . . . " 21 U.S.C. § 360(a)(1). "Distribution" is delivery by a manufacturer to a middleman, while "dispensing" is the act of a pharmacist transferring the drug directly to the patient pursuant to a prescription. Pharmacy compounding results in dispensing. Manufacturing and compounding are not defined in the FDCA, except to the extent that §§ 360(g)(1) and 374(a)(2)(A) provide benchmark characteristics and even then, for definitional purposes, revert back to and rely on State laws.

All States define and regulate the practice of pharmacy within their borders.[4] Twenty-six States

[4] Ala. Code § 34-23-1 *et seq.* (2001); Alaska Stat. § 8.80.003 *et seq.* (Michie 2001); Ariz. Rev. Stat. Ann. § 32-1901 *et seq.* (West 2001); Ark. Code Ann. § 17-92-101 *et seq.* (Michie 2001); Cal [Bus. Prof.] Code § 4000 *et seq.* (Deering 2001); Colo. Rev. Stat. Ann. § 12-22-01 *et seq.* (West 2001); Conn. Gen. Stat. § 20-570 *et seq.* (2001); Del. Code Ann. Tit. 24, § 2501 *et seq.* (2001); D.C. Code Ann. § 48-701 *et seq.* (2001); Fla. Stat. Ch. 465.001 *et seq.* (2001); Ga. Code Ann. § 26-4-1 *et seq.* (Harrison 2001); Haw. Rev. Stat. Ann. § 461-1 *et seq.* (Michie 2001); Idaho Code § 54-1701 *et seq.* (Michie 2000); 225 Ill. Comp. Stat. Ann. 85/1 *et seq.* (West 2001); Ind. Code Ann. § 25-26-13 *et seq.* (Michie 2001); Iowa Code § 155A.1 *et seq.* (2001); Kan. Stat. Ann. § 65-1625 *et seq.* (2001); Ky. Rev. Stat. Ann. § 315.002 *et seq.* (Michie 2001); La. Rev. Stat. Ann. § 1161 *et seq.* (West 2000); Me. Rev. Stat. Ann. Tit. 32 § 13701 *et seq.* (West 2001); Md. Code Ann., [Health Occ.] § 12-101 *et seq.* (2001); Mass. Ann. Laws ch. 94C, § 1 *et seq.* (Law. Co-op. 2001); Mich. Comp. Laws Ann. § 333.17701 *et seq.* (West 2001); Minn. Stat. § 151.01 *et seq.* (2000); Miss. Code Ann. § 73-21-71 *et seq.* (2001); Mo. Rev. Stat. § 338.010 *et seq.* (2001); Mont. Code Ann. § 37-7-101 *et seq.* (2001); Neb. Rev. Stat. Ann. § 71-1,142 *et seq.* (Michie 2001); Nev. Rev. Stat. Ann. 639.001 *et seq.* (Michie 2001); N.H. Rev. Stat. Ann. § 318.1 *et seq.* (2001); N.J. Stat. Ann. § 45:14-1 *et seq.* (West 2001); N.M. Stat. Ann. § 61-11-1 *et seq.* (Michie 2001); N.Y. [Educ.] Law § 6800 *et seq.* (Consol. 2001); N.C. Gen. Stat. § 90-85.2 *et seq.* (2000); N.D. Cent. Code § 43-15-01 *et seq.* (2001); Ohio Rev. Code Ann. § 4729.01 *et seq.* (West 2001); Okla. Stat. tit. 59, § 353-1 *et seq.* (2001); Or. Rev. Stat. § 689.005 *et seq.* (1999); 63 Pa. Stat. Ann. § 390-1 *et seq.* (West 2001); R.I. Gen. Laws § 5-19.1-1 *et seq.* (2001); S.C. Code Ann. § 40-43-10 *et seq.* (Law. Co-op. 2001); S.D. Codified Laws § 36-11-1 *et seq.* (Michie 2001); Tenn. Code Ann. § 63-10-401 *et seq.* (2001); Tex. [Occ.] Code Ann. § 551.001 *et seq.* (Vernon 2001); Utah Code Ann. § 58-17a-101 *et seq.* (2001); Vt. Stat. Ann. tit. 26, § 2021 *et seq.* (2001); Va. Code Ann. § 54.1-3401 *et seq.* (Michie 2001); Wash. Rev. Code Ann. § 18.64.001 *et seq.* (West 2001); W. Va. Code Ann. § 30-5-1 *et seq.* (Michie 2001); Wis. Stat. Ann. § 450.01 *et seq.* (West 2001); Wyo. Stat. Ann. § 33-24-101 *et seq.* (Michie 2001).

also require that out-of-state pharmacies dispensing to patients in their States register in their States and subject themselves to their enforcement.[5] States define

[5] Alaska Stat. § 8.80.158 (Michie 2001); Ark. Code Ann. § 17-92-401 (Michie 2001); Cal [Bus. Prof.] Code § 4112 (Deering 2001); Conn. Gen. Stat. § 20-627 (2001); Del. Code Ann. Tit. 24, § 2538 (2001); Fla. Stat. Ch. 465.0156 (2001); 225 Ill. Comp. Stat. Ann. 85/16a (West 2001); Ind. Code Ann. § 25-26-17-3 (Michie 2001); Iowa Code § 155A.13a (2001); Kan. Stat. Ann. § 65-1657 (2001); Ky. Rev. Stat. Ann. § 315.0351 (Michie 2001); Md. Code Ann., [Health Occ.] § 12-403 (2001); Minn. Stat. § 151.19 (2000); Miss. Code Ann. § 73-21-106 (2001); Mont. Code Ann. § 37-7-703 (2001); Nev. Rev. Stat. Ann. 639.2328 (Michie 2001); N.M. Stat. Ann. § 61-11-14.1 (Michie 2001); N.Y. [Educ.] Law § 6808-b

manufacturing[6] and

(Consol. 2001); N.C. Gen. Stat. § 90-85.21a (2000); N.D. Cent. Code § 43-15-34.1 (2001); Okla. Stat. tit. 63, § 2-302 (2000); R.I. Gen. Laws § 5-19.1-11 (2001); S.D. Codified Laws § 36-11-19.3 (Michie 2001); Va. Code Ann. § 54.1-3434.1 (Michie 2001); Wash. Rev. Code Ann. § 18.64.360 (West 2001); Wyo. Stat. Ann. § 33-24-152 (Michie 2001).

An example is Illinois' statute which provides that, "[t]he Board shall require and provide for an annual nonresident special pharmacy registration for all pharmacies located outside of [Illinois] that dispense medications for Illinois residents and mail, ship, or deliver prescription medications into [Illinois]." 225 Ill. Comp. Stat. Ann. 85/16a(b) (West 2001).

[6] Ala. Code § 34-23-1(11) (2001); Alaska Stat. § 8.80.480(15) (Michie 2001); Ariz. Rev. Stat. Ann. § 32-1901(27) (West 2001); Ark. Code Ann. § 20-64-201(5) (Michie 2001); Cal [Bus. Prof.] Code § 4033 (Deering 2001); Colo. Rev. Stat. Ann. § 12-22-102(17) (West 2001); Conn. Gen. Stat. § 21-240(28) (2001); Del. Code Ann. tit. 24, § 2502 (2001); D.C. Code Ann. § 48-701(3) (2001); Fla. Stat. ch. 499.003(21) (2001); Ga. Code Ann. § 26-4-5(23) (Harrison 2001); Haw. Rev. Stat. Ann. § 328-112 (Michie 2001); Idaho Code § 54-1705(17) (Michie 2000); 225 Ill. Comp. Stat. Ann. 120/15 (West 2001); Ind. Code Ann. § 16-18-2-216 (Michie 2001); Iowa Code § 124.101(16) (2001); Kan. Stat. Ann. § 65-1626(q) (2001); Ky. Rev. Stat. Ann. § 315.010(12) (Michie 2001); La. Rev. Stat. Ann. § 1164(25) (West 2000); Me. Rev. Stat. Ann. tit. 32 § 13702(14) (West 2001); Md. Ann. Code art. 27, § 277 (2001); Mass. Ann. Laws ch. 94C, § 1 (Law. Co-op. 2001); Mich. Comp. Laws Ann. § 333.17706(1) (West 2001); Minn. Stat. § 151.01(Subd. 14) (2000); Miss. Code Ann. § 73-21-73(s) (2001); Mo. Rev. Stat. § 195.010(23) (2001); Mont. Code Ann. § 37-7-101(17) (2001); Neb. Rev. Stat. Ann. § 28-401(14) (Michie 2001); Nev. Rev. Stat. Ann. 639.009 (Michie 2001); N.H. Rev. Stat. Ann. § 318.1(viii) (2001); N.J. Stat. Ann. § 24:6B-12(f) (West 2001); N.M. Stat. Ann. § 61-11-2(Q) (Michie 2001); N.Y. [Educ.] Law § 6802(21) (Consol. 2001); N.C. Gen. Stat. § 90-87(15) (2000); N.D. Cent. Code § 43-15-01(13) (2001); Ohio Rev. Code Ann.

compounding,[7] while neither is defined in the FDCA or FDAMA.

§ 3715.01(14) (West 2001); Okla. Stat. tit. 59, § 351.1(20) (2001); Or. Rev. Stat. § 689.005(19) (1999); 35 Pa. Stat. Ann. § 780-102 (West 2001); R.I. Gen. Laws § 5-19.1-2(n) (2001); S.C. Code Ann. § 40-43-30(29) (Law. Co-op. 2001); S.D. Codified Laws § 34-20B-1(11) (Michie 2001); Tenn. Code Ann. § 63-10-404(18) (2001); Tex. [Occ.] Code Ann. § 551.003(23) (Vernon 2001); Utah Code Ann. § 58-17a-102(22) (2001); Vt. Stat. Ann. tit. 18, § 4201(14) (2001); Va. Code Ann. § 54.1-3401 (Michie 2001); Wash. Rev. Code Ann. § 18.64.011(20) (West 2001); W. Va. Code Ann. § 30-5-1b(o) (Michie 2001); Wis. Stat. Ann. § 450.01(13) (2001); Wyo. Stat. Ann. § 35-7-1002(xiii) (Michie 2001).

[7] Alaska Stat. § 8.80.480(3) (Michie 2001); Ariz. Rev. Stat. Ann. § 32-1901(7) (West 2001); Colo. Rev. Stat. Ann. § 12-22-102(6) (West 2001); Conn. Gen. Stat. § 20-571(5) (2001); Ga. Code Ann. § 26-4-5(4) (Harrison 2001); Haw. Rev. Stat. Ann. § 328-112 (Michie 2001); Idaho Code § 54-1705(17) (Michie 2000); 225 Ill. Comp. Stat. Ann. 85/3(o) (West 2001); Ky. Rev. Stat. Ann. § 315.010(5) (Michie 2001); La. Rev. Stat. Ann. § 1164(5) (2000); Me. Rev. Stat. Ann. tit. 32 § 13702(2-A) (West 2001); Md. Code Ann., [Health Occ.] § 12-101(d) (2001); Miss. Code Ann. § 73-21-73(c) (2001); Mont. Code Ann. § 37-7-101(7) (2001); Neb. Rev. Stat. Ann. § 71-1,142(7) (Michie 2001); Nev. Rev. Stat. Ann. 639.0053 (Michie 2001); N.H. Rev. Stat. Ann. § 318.1(III-a) (2001); N.M. Stat. Ann. § 61-11-2(C) (Michie 2001); N.C. Gen. Stat. § 90-85.3(c) (2000); N.D. Cent. Code § 43-15-01(3) (2001); Ohio Rev. Code Ann. § 4729.01(C) (West 2001); R.I. Gen. Laws § 5-19.1-2(c) (2001); S.C. Code Ann. § 40-43-30(7) (Law. Co-op. 2001); S.D. Codified Laws § 36-11-2(5) (Michie 2001); Tenn. Code Ann. § 63-10-404(4) (2001); Tex. [Occ.] Code Ann. § 551.003(9) (Vernon 2001); Utah Code Ann. § 58-17a-102(6) (2001); Va. Code

SUMMARY OF ARGUMENT

FDAMA's advertisement and solicitation restrictions fail this Court's test for commercial speech restrictions established in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980) and, therefore, violate the First Amendment. The parties agree, here and in the courts below, that Respondents' advertisements and solicitations are truthful and non-misleading. In the court below, Petitioners agreed that the introduction of compounds interstate was legal, a position they no longer maintain in this Court.

Petitioners do not have a substantial interest in "preventing manufacturing under the guise of compounding" because Petitioners' purported interest is based on a false premise. The false premise is that pharmacy compounding in compliance with State laws can ever be manufacturing or that they can be differentiated by volume. Petitioners' erroneous position disregards the differences between manufacturing and compounding and falsely attributes advertising and soliciting solely to manufacturing.

In an attempt to achieve that goal, Section 353a restricts truthful, non-misleading speech; however, Respondents' advertising and soliciting do not drive demand for compounded drugs; patients' needs as determined by physicians' prescriptions drive that demand. Advertising informs the physician of the availability of

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Ann. § 54.1-3401 (Michie 2001); Wash. Rev. Code Ann. § 18.64.011(18) (West 2001); W. Va. Code Ann. § 30-5-1b(c) (Michie 2001); Wis. Stat. Ann. § 450.01(3) (West 2001).

compounded drugs to satisfy a pre-existing patient need. Moreover, the Petitioners, by their own admission, will allow advertising of compounding services, just not of particular compounded drugs, classes of drugs, or types of drugs. Consequently, even were we to assume, *arguendo*, that a restriction prohibiting advertising of services and specific drugs, classes, and types could measurably reduce the demand for compounded drugs, it is doubtful that the FDAMA speech ban on specific drugs, classes, and types could achieve that goal. Further, regardless of the speech restrictions, the many exceptions to FDAMA allow widespread dispensing of compounded drugs such that the advertisement and solicitation restrictions do little to advance Petitioners' asserted interest.

The absolute speech restrictions in §§ 353a(a) and (c) are more extensive than necessary to accomplish Petitioners' purported interest. The Ninth Circuit correctly recognized less intrusive options that would advance Petitioners' interest. For example, disclaimers explaining that compounded drugs did not have FDA approval would accomplish Petitioners' interest without abridging Respondents' First Amendment rights. Petitioners rationalize that compounds are "new drugs" and, therefore, must be put through a new drug approval process.

The FDCA never recognized compounds as new drugs, and the FDA's prior conduct is consistent with this position. Pharmacy compounding is specifically exempted from the FDCA by 21 U.S.C. §§ 360(a)(1), 360(g)(1), and 374(a)(2)(A). It is inconceivable that Petitioners, other than for the purpose of this appeal, genuinely consider interstate dispensing of compounds illegal. As Petitioners admit in their brief, they steadfastly and

historically have refrained from controlling or regulating compounding, and openly acknowledge the desirability of compounding in the niches where manufactured drugs are unavailable. Petitioners assert that "[b]efore 1997, the introduction of compounded new drugs into interstate commerce – like the introduction of all other unapproved new drugs – was unlawful in all circumstances." (Pets.' Br. 18.) They are wrong and ignore the FDA's own complete lack of regulation or enforcement activity towards pharmacies.

The advertisement and solicitation restrictions in Section 353a do nothing more than prevent the dissemination of admittedly truthful, non-misleading information to physicians and patients. Capping the volume of compounds cannot be accomplished by restrictions on advertising or soliciting. Such volume restrictions are provoked by physicians' judgments of patients' needs. The information disseminated is not just advertising, but also educational, *i.e.*, it informs physicians and patients of what is capable of being compounded.

Petitioners cannot condition exemption from FDCA requirements on Respondents' relinquishment of their Constitutional rights because the First Amendment protects Respondents from the Petitioners' attempt to regulate conduct by suppressing speech.

ARGUMENT

I. THE COURTS BELOW CORRECTLY HELD THAT THE RESTRICTIONS ON TRUTHFUL AND NON-MISLEADING ADVERTISEMENT AND SOLICITATION CONTAINED IN SECTIONS 353a(a) AND (c) VIOLATE THE FIRST AMENDMENT

A. Petitioners Have The Burden Of Satisfying The *Central Hudson* Criteria

The parties agree, and the courts below held, that Respondents' advertisements and solicitations constitute commercial speech and that the First Amendment issues in this case are controlled by *Central Hudson* and its progeny. Petitioners also concede that Respondents' advertisements and solicitations are truthful and not misleading.[8] (Pets.' Br. 18.) For the restrictions on advertisement and solicitation in §§ 353a(a) and (c) to pass First Amendment scrutiny, they must satisfy the four *Central Hudson* criteria: (1) the speech at issue must concern lawful activity and not be inaccurate or misleading; (2) the asserted governmental interest must be substantial; (3) the law challenged must directly and materially advance the asserted governmental interest; and (4) the law must accomplish the asserted ends in a manner that is not more extensive than necessary. 447 U.S. at 566. *See also 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 499-500, 529 (1996).

The parties also agree that "[t]he government has the burden of justifying a commercial speech restriction."

[8] Samples of Respondents' advertisements are in the record. (Grp. Exh. 2 to Verified Compl.)

(Defs.' Mot. Summ. J., at 12.) It has been difficult to pin down Petitioners' position as to whether the introduction of compounds into interstate commerce is legal. In this Court, they say it is "unlawful in all circumstances." (Pets'. Br. 18.) Yet, this is not the position that the district court or the Ninth Circuit understood Petitioners to have taken. The district court found, "[i]n this case, Defendants do not argue that the restrictions at issue involve illegal activity; rather they contend that the targeted speech is misleading." (Pets.' App. 32a; to the same effect, *see*, Defs.' Resp. to Interrogs., ¶ 2.) The Ninth Circuit held, "[o]n appeal, the government does not contend that the prohibited speech is unlawful or misleading." (Pets.' App. 5a.) The parties disagree whether Petitioners have met their burden in showing that the soliciting and advertising restrictions at issue satisfy the second, third and fourth *Central Hudson* criteria.

Central Hudson requires that Petitioners may restrict speech only upon a showing of a substantial interest and that the restriction directly and materially advances the substantial interest in a manner no more extensive than necessary. 447 U.S. at 566. Mere speculation or conjecture by the government in attempting to meet its burden will not suffice. *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993). "The State's burden is not slight. . . . [It] must demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree." *Ibanez v. Florida Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 143 (1994). Petitioners cannot satisfy their weighty burden, as they have attempted to here, with arguments that "amount to little more than unsupported assertions." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 649

(1985); *44 Liquormart, Inc.*, 517 U.S. at 504; *Edenfield*, 507 U.S. at 769.

Petitioners suggest that this Court has *sub silentio* overruled *Edenfield*, *Ibanez* and *Zauderer* and lessened their burden to one based "solely on history, consensus, and 'simple common sense.' " (Pets.' Br. 30.) Petitioners base this claim upon *Lorillard Tobacco Co. v. Reilly*, 121 S. Ct. 2404 (2001). In *Lorillard*, this Court, relying on *Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995) stated that, "[w]e have permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and "simple common sense." 121 S. Ct. at 2422, *quoting Florida Bar v. Went For It, Inc.*, 515 U.S. at 628 (citations and internal quotations omitted). However, in *Florida Bar*, unlike here, significant studies were introduced at trial to support the problem addressed. 515 U.S. at 635. Similarly, in *Lorillard*, this Court's review revealed substantial documentation of the problem of underage use of smokeless tobacco and cigars. 121 S. Ct. at 2408. The record here is void of a basis in common sense, let alone proof, that the speech restrictions directly and materially advance the government's purported interest in lessening compounding activity.

In *Florida Bar*, this Court relied upon *Burson v. Freeman*, 504 U.S. 191 (1992), and upheld the limited prohibition on the solicitation of votes within 100 feet of the entrance to a polling place on election day. *See Burson*, 504 U.S. at 211. In balancing two important constitutional rights, free speech and the right to vote, this Court said

that "because a government has such a compelling interest in securing the right to vote freely and effectively, this Court never has held a State 'to the burden of demonstrating empirically the objective effects on political stability that [are] produced' by the voting regulation in question." *Burson*, 504 U.S. at 208, *citing Munro v. Socialist Workers Party*, 479 U.S. 189, 195 (1986). Neither *Lorillard*, *Florida Bar*, nor *Burson* support Petitioners' contention that "common sense" can substitute for evidence to support Petitioners' claim that the dispensing of compounded drugs significantly increases demand for compounding beyond what it would otherwise be, allegedly endangering health. "Such speculation certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends." *44 Liquormart, Inc.*, 517 U.S. at 507.

B. Petitioners Have Not Shown That They Have A Substantial Interest

Petitioners claim that the challenged restrictions on truthful speech are justified because they advance Petitioners' interest to a material degree in "preventing compounding that is tantamount to manufacturing" which, if permitted, would threaten to undermine the new drug approval process. (Pets.' Br. 31; *see also* similar claims at Pets.' Br. 13, 14, 28, 33, 34, 35, 40, 43.) Petitioners never define the point at which compounding ends and manufacturing begins, making the assessment impossible due to want of necessary facts and criteria.

Petitioners' argument is premised on an assumption that compounding is capable of being done on a scale

tantamount to manufacturing. (Pets.' Br. 28.) However, regardless of volume, compounding can never be manufacturing and manufacturing can never be compounding. They are not defined in Title 21 of the United States Code, and notwithstanding Petitioners' Interrogatory Answer, "State law is irrelevant to this case" (Defs.' Resp. to Interrog. ¶ 1), these terms are defined under State law. Typically, States define manufacturing as the production of a drug to meet an identified generalized patient need, delivered to distributors and wholesalers who sell to pharmacies which dispense to patients.[9] The manufacturer plays no role in the triad, receives no prescriptions, and does not dispense. In contrast, under State laws, pharmacists compound and dispense.[10] Hence, compounding is incapable of ever being tantamount to manufacturing. Additionally, if and when demand for a compound ever increases to a level where manufacturing becomes practical (*i.e.*, profitable), a manufacturer may bring it to market, whereupon pharmacies will stop making it. Petitioners advocate that a characteristic of manufacturing is volume. No State or federal law supports this *leitmotif*.

The FDCA and FDAMA do not define "compounding" or "manufacturing" and State pharmacy codes do not draw upon volume as a distinguishing characteristic. For example, under the Wisconsin Pharmacy Code, "manufacturing" is defined as the "distribution of the drug . . . from the original place of manufacture to the person

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[9] *See* footnote 6, *supra*.

[10] *See* footnote 7, *supra*.

who makes final delivery or sale to the ultimate consumer." Wis. Stat. Ann. § 450.01(13). "Manufacturing" contemplates distribution by an individual or entity which is never the patient. "Compound" means to "mix, combine or put together various ingredients or drugs for the purpose of dispensing," Wis. Stat. Ann. § 450.01(3), and "dispense" is defined as "to deliver a prescribed drug . . . to an ultimate user. . . . " Wis. Stat. Ann. § 450.01(7).

Petitioners' unsupported assertion, "that advertising of particular drug products is a business practice that is characteristic of manufacturing, but not of traditional compounding by a pharmacy for an individual need" (Pets.' Br. 33) so that "[e]xpenditures on such advertising therefore are a fair proxy for actual or intended large scale manufacturing" (Pets.' Br. 35) is belied by the pharmacy codes of the 50 states. Even if manufacturers advertise, it does not follow that pharmacies do not or that patients and physicians should be prohibited from receiving truthful information. Blanket bans on commercial speech are disfavored. *See 44 Liquormart, Inc.*, 517 U.S. at 500-502, *quoting Central Hudson*, 447 U.S. at 566, n.9 ("[S]pecial concerns arise from 'regulations that entirely suppress commercial speech in order to pursue a non-speech related policy.' ").

The district court's opinion rejecting Petitioners' argument on this subject is a cogent statement of the fallacy of the government's position:

> The court is not convinced, however, that [Petitioners] have a substantial interest in preventing 'compounding under the guise of manufacturing.' [Petitioners] have offered no definition of

> either manufacturing or compounding, apparently because the Modernization Act itself offers no such definition. Thus, there is no coherent way for this court to determine whether [Petitioners] have a substantial interest in encouraging one while limiting the other. In their argument, [Petitioners] appear to equate high volume distribution with manufacturing and low volume distribution with compounding. In their Motion, they insist that they must "limit the volume of compounding because of the increased health risks associated with a large number of patients receiving drugs that are not subject to the same quality control standards that apply to ordinary manufactured drugs." [Petitioners]' Motion at 21. This framework, however, obviously cannot support [Petitioners]' asserted interest in preventing compounding allegedly done under the guise of manufacturing. First, it does nothing to clarify the difference between manufacturing and compounding. Furthermore, even were the distinction clear, this argument neither explains nor supports the contention that there are "increased health risks associated with a large number of patients" receiving compounded drugs, but that compounded drugs in small quantities produce an overall benefit to the public health.
>
> If, on the other hand, [Petitioners] believe that the relevant distinction is between those drugs that are FDA approved and those that are not, the court agrees that the FDA has a legitimate interest in preventing pharmacists from circumventing FDA requirements by changing the description of their products. To the extent this

is the basis for [Petitioners]' distinction, the court agrees that it is substantial. The problem with this argument is that without more, it ultimately reduces to equating manufacturing with approved drugs and compounding with unapproved drugs. At that point, any interest [Petitioners] assert in making compounded drugs available to individual patients is no long tenable. Therefore, on the facts before it, the court is unable to either identify or acknowledge the significance of the distinction between manufactured and compounded drugs.* For this reason, it cannot agree with [Petitioners] that the Government has a substantial interest in achieving the imprecise and undefined balance it purportedly seeks here.

* * *

(Pets.' App. 42a-44a.)

> In reality, the practical difference in this case between [Petitioners]' notion of manufacturing and compounding may actually be embodied by the precise issue the court must address in this order. Specifically, it appears that [Petitioners] would label pharmacy-initiated drug combining as manufacturing, and patient- or physician-initiated drug combining as compounding. This frames the distinction by looking to whether the pharmacist or other drug producer advertised, promoted or otherwise initiated the sale and use of the particular drug product. Of course, to accept [Petitioners]' distinction, and more importantly, to accept that [Petitioners] have a substantial interest in preserving this distinction, is to agree that [Petitioners] have a substantial interest in preventing

> pharmacists from advertising or promoting particular compounded drugs, because to allow such promotion would be to allow pharmacists to manufacture under the guise of compounding. This conclusion begs the question before the court, which is whether the speech restrictions contained in § 353a are legitimate.

(Pets.' App. 43a, n.9.)

C. Petitioners Have Not Shown That The Restrictions On Respondents' Truthful And Non-Misleading Advertising And Soliciting Materially Advance Petitioners' Asserted Interests

1. FDA's prior enforcement actions are irrelevant to the unconstitutionality of the challenged restrictions but do reveal that the FDA did not consider "compounding" to be "manufacturing"[11]

Petitioners argue that prior to the enactment of FDAMA, the FDA was enforcing the law in a manner consistent with FDAMA and that FDAMA merely brought "the legal status of compounding in line with FDA's longstanding enforcement policy of regulating only drug manufacturing, not ordinary pharmacy compounding." (Pets.' Br. 6, *quoting* 143 Cong. Rec. S 9811-04 at S 9839 (daily ed. Sept, 24, 1997) (Statement of Sen. Kennedy).) Petitioners rely upon the CPG and cases cited at page 36 of their brief to support their claim that before

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[11] Respondents contest that the FDA has jurisdiction over compounded drugs as they are not "new drugs" under § 321(p)(1), and the FDA's prior non-enforcement is relevant to the analysis of whether compounds are new drugs.

FDAMA, the interstate dispensing of compounds was not permitted. (Pets.' Br. 6, 32-33, 36.) The cases cited by Petitioners at page 36 of their brief are silent on the proposition for which they have been cited and have nothing to do with compounded drugs or truthful and non-misleading advertisements.

Petitioners' reliance on its own enforcement of the FDCA before FDAMA to establish that its enforcement met Constitutional standards is misplaced. First, the CPG itself did not make the advertising or soliciting of compounded drugs illegal. It was a statement of FDA enforcement policy that itself revealed the FDA to have deemed compounding not illegal manufacturing when conducted in conformance with the nine CPG factors. Second, the CPG was not law. It was merely an unenforceable internal guide for FDA field agents. *See Professionals & Patients for Customized Care v. Shalala*, 847 F. Supp. 1359, 1363-64 (S.D. Tex. 1994), *aff'd* at 56 F.3d 592 (5th Cir. 1995) ("*PPCC*"). As the court in *PPCC* held, "a policy statement announces the agency's tentative intentions for the future." 56 F.3d at 596.

Courts have not hesitated to declare illegal the enforcement policies of the FDA based on internal guidelines. *See, e.g., FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (invalidating FDA's regulations over tobacco); *Pearson v. Shalala*, 164 F.3d 650, 661 (D.C. Cir. 1999) (invalidating on First Amendment grounds FDA regulation regarding diet supplements); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 74 (D.D.C. 1998) (invalidating on First Amendment grounds policies of FDA and HHS restricting off-label uses of FDA-approved drugs and devices); *Washington Legal Found. v.*

Friedman, 36 F. Supp. 2d 16 (D.D.C. 1999); *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81, 87 (D.D.C. 1999) (finding FDA's policies restricting the dissemination of articles and texts relating to off-label use in violation of the First Amendment, *vacated at* 202 F.3d 331 (D.C. Cir. 2000) because FDA conceded on appeal that it had no authority to prosecute manufacturers for violating a normative standard set forth in FDAMA or the guidelines for continuing medical education).

2. The power to regulate compounding, a commercial activity, does not include the power to restrict advertising, promoting, and soliciting

If compounded drugs filled in response to a physician's prescription are dangerous, then compounding should be outlawed. Yet, State pharmacy codes and pharmacy schools mandate compounding equipment and skills, compounding is specifically exempted by federal statutes, the FDA left compounding alone for at least 59 years, and Petitioners praise compounding, conceding its importance and necessity. Nonetheless, Petitioners struggle to withhold truthful, non-misleading information about an acclaimed and legal activity.

This Court has made it clear that the government may not employ restrictions on accurate commercial speech about lawful activity to regulate the underlying activity which the government seeks to affect. As this Court stated in *44 Liquormart*:

> . . . we think it quite clear that banning speech may sometimes prove far more intrusive than

> banning conduct. . . . In short, we reject the assumption that words are necessarily less vital to freedom than actions, or that logic somehow proves that the power to prohibit an activity is necessarily "greater" than the power to suppress speech about it.

517 U.S. at 511. *See also Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 773 (1976) (holding that a State may not "completely suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of that information's effect upon its disseminators and its recipients.").

Petitioners argue that the advertising and soliciting restrictions advance a substantial governmental interest in that reducing advertising will reduce demand, thereby protecting the public health from compounded drugs. (Pets.' Br. 35.) This Court has consistently rejected this rationale as a justification for limitations upon advertising. *See, e.g., 44 Liquormart, Inc.*, 517 U.S. at 500, n.10 (striking down two Rhode Island statutes that prohibited the advertising of alcoholic beverage retail prices anywhere other than at point of purchase); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 491 (1995) (invalidating federal statute that prohibited brewers from disclosing on labels the alcoholic content of their beers); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 772 (1975) (declaring unconstitutional a Virginia statute that made it unprofessional for a pharmacist to advertise the prices of prescription drugs). *See also Valley Broad. Co. v. United States*, 107 F.3d 1328 (9th Cir. 1997); *Carey v. Population Serv. Int'l.*, 431 U.S. 678 (1977); *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977); *but cf., Greater*

New Orleans Broad. Ass'n v. United States, 527 U.S. 173, 188-89 (1999) (holding unconstitutional statute and regulations that prohibited radio and television broadcasters from carrying advertisements about privately operated commercial casino gambling but recognizing government's interest in alleviating casino gambling's social costs by limiting demand).

The assertion that speech restrictions advance the public health has been rejected by the D.C. Circuit in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). In *Pearson*, the FDA argued that the health of consumers was directly advanced by barring health claims about dietary supplements not approved by the FDA. *Pearson*, 164 F.3d at 656. Here, in a rehash of their position rejected in *Pearson*, Petitioners argue that the health of consumers is advanced by barring all advertisements of compounded drugs because they have not been approved by the FDA. In rejecting the FDA's argument in *Pearson*, the D.C. Circuit wrote:

> The government simply asserts its 'common sense judgment' that the health of consumers is advanced *directly* by barring any health claims not approved by the FDA. Because it is not claimed that the product is harmful, the government's underlying – if unarticulated – premise must be that consumers have a limited amount of either attention or dollars that could be devoted to pursuing health through nutrition, and therefore products that are not indisputably health enhancing should be discouraged as threatening to crowd out more worthy expenditures. We are rather dubious that this simplistic view of human nature or market behavior is sound, but, in any event, it surely cannot be said

> that this notion – which the government does not even dare openly to set forth – is a *direct* pursuit of consumer health; it would seem a rather indirect route, to say the least.

164 F.3d at 656.

3. Patient need and physician judgment drive demand for compounds, not advertisement, promotion, and solicitation

No matter how widely Respondents truthfully advertise particular drugs, classes and types of drugs, patients cannot obtain a compounded drug without a valid prescription from a licensed physician. To the extent advertising drives demand for compounds, the judgment of the prescribing physician serves as a brake. Unlike consumer products for which demand can be artfully hyped, advertising compounded drugs merely informs physicians and patients about the availability of compounds, but only to meet a pre-existing medical need. In the triad, the pharmacist is not a pitchman, but a learned professional. The pharmacist educates the physician of treatment opportunities which the physician may then prescribe but only upon diagnosis of a patient with that particular need.

Petitioners offered no evidence that Section 353a's advertisement and solicitation restrictions would directly and materially further the government's goal to reduce demands for compounds. As this Court observed when considering gambling advertising, "[w]hile it is no doubt fair to assume that more advertising would have some

impact on overall demand for gambling, it is also reasonable to assume that much of that advertising would merely channel gamblers to one casino, rather than another." *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 189 (1999). The speech restrictions in Section 353a do not directly and materially advance the government's purported interest.

4. Petitioners have not demonstrated that the challenged speech restrictions will materially prevent a circumvention of the drug approval process

Petitioners claim that the speech and advertising restrictions contained in §§ 353a(a) and (c) will prevent circumventing the new drug approval process. Petitioners rely upon *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 653 (1973), in which this Court noted "that it would be 'inherently unfair' to require compliance by one manufacturer with the new drug approval requirements 'while his competitors marketing similar drugs remain free to violate the Act.' " (Pets.' Br. 29.) Manufacturers and pharmacists do not compete, and Petitioners offered no evidence of this mythical competition. By definition, pharmacies only compound in the absence of a suitable manufactured product. (Verified Compl., ¶ 21(a).) It ill behooves Petitioners to complain that compounds bypass the new drug approval process. Compounds were never subject to the new drug approval process, which would not have changed under FDAMA. The only change would have been the imposition of First Amendment restrictions which would not have directly and materially protected the new drug approval process.

Petitioners claim that the advertisement and solicitation restrictions protect the public because public health risk increases when more patients use compounded drugs.[12] (Pets.' Br. 30.) In the lower courts, Petitioners based this claim on one anecdotal incident reported as hearsay in the CPG. In this Court, Petitioners again rely upon this isolated anecdotal incident. (Pets.' Br. 28.) As the court recognized in *United States v. Sene X Eleemosynary Corp., Inc.*, 479 F. Supp. 970, 976 (S.D. Fla. 1979), *aff'd*, [1982-1983 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,207 (11th Cir. 1983), such "anecdotal evidence . . . is the poorest form of evidence." In *Weinberger v. Hynson, Westcott & Dunning, Inc.*, this Court characterized anecdotal evidence as "treacherous." 412 U.S. 609, 629-630 (1973). Speculative conjecture will not satisfy Petitioners' burden in justifying the speech and advertising restrictions at issue. *Ibanez v. Florida Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 141-142 (1994); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 647 (1985).

5. FDAMA is so riddled with exceptions that it cannot directly and materially advance Petitioners' asserted interest

When a statutory or regulatory scheme is "so pierced by exemptions and inconsistencies, [ ] the Government cannot hope to exonerate it." *Greater New Orleans Broad. Ass'n*, 527 U.S. at 190. Petitioners' aim is to suppress the

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[12] The cases relied upon by Petitioners at footnote 4 of their brief are irrelevant here. They had nothing to do with compounding by a licensed pharmacist, and none were First Amendment cases.

volume of compounded drugs. Yet, regardless of the speech restrictions, FDAMA permits widespread compounding.

FDAMA permitted pharmacies to dispense unlimited quantities of prescription drugs intrastate. Moreover, nothing made it illegal for patients to cross state lines and purchase compounds in a neighboring state, and FDAMA did not prevent a physician from prescribing a compound in any quantity or frequency.

The MOU provisions did nothing to stem interstate dispensing. Pursuant to § 353a(b)(3)(B), if a compounding pharmacist's State did not enter into an MOU, a pharmacist could dispense compounds interstate up to 5% of total prescription orders. With an MOU, the pharmacist would be permitted to dispense compounds interstate up to 19.9% of total prescription orders.

With their numerous sites, chain drug stores (Walgreens, CVS, *etc.*) could single-handedly endrun the percentages and supply 100% of the demand. Also, to avoid the 5% or 19.9% limitations, pharmacies could merely refer prescriptions over their limit to another pharmacy. That pharmacies can dispense compounds without limits but cannot advertise or solicit their compounds indicates the irrationality of FDAMA's regulatory scheme. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488 ("The failure to prohibit the disclosure of alcohol content in advertising, which would seem to constitute a more influential weapon in any strength war than labels, makes no rational sense if the Government's true aim is to suppress strength wars.").

FDAMA was ill-conceived because the 5% and 19.9% represent a percentage of each pharmacy's total prescription orders. Pharmacies that compound as a specialty and have few sales other than compounds would never have a gross order figure from which to make the calculation, because they would not be able to make a sale of a compound without first making sales of non-compounded drugs.

D. Section 353a Does Not Accomplish The Asserted Ends In A Manner That Is No More Extensive Than Necessary

The Ninth Circuit correctly found that "the speech restrictions fail the fourth *Central Hudson* factor; they are more extensive than necessary to achieve the asserted government interest." (Pets.' App. 10a.) In the district court, Petitioners argued that the speech restrictions were necessary to protect the public from being misled into believing that they were taking prescription drugs that had been approved by the FDA. (Defs.' Mot. Summ. J. at 16-17.) This argument has since been abandoned. The district court and the Ninth Circuit recognized that disclaimers could accompany compounded drugs, explaining that they had not been FDA approved. The availability of options which could advance Petitioners' asserted interests in a manner less intrusive of Respondents' First Amendment rights indicates that the speech restrictions are more extensive than necessary. *See Rubin v. Coors Brewing Co.*, 514 U.S. at 491.

Petitioners now complain that disclaimers would not prevent "widespread distribution of drugs that have not

been demonstrated to be safe and effective." (Pets.' Br. 45.) The disclaimer was in response to Petitioners' lower court argument that compounds are inherently misleading, *i.e.*, that they somehow suggest FDA approval. The speech restrictions are far broader than necessary, while at the same time do little, if anything, to limit compounded drugs.

Petitioners argue that the challenged restrictions on truthful speech are limited intrusions upon advertising and soliciting because the statute permits Respondents to advertise "that they perform compounding services, that they are experts in compounding, and that they stand ready to fill prescriptions for compounded drug products." (Pets.' Br. 43.) The restrictions on truthful advertising and soliciting contained in § 353a(c) are absolute restrictions upon truthful speech. Section 353a(c) provides that Respondents may not "advertise or promote the compounding of any particular drug, class of drug or type of drug." 21 U.S.C. § 353a(c). It restricts all advertising and soliciting on those topics, whether made in the pharmacy, at seminars, *etc.* Those restrictions prevent the very types of advertisement and promotion that this Court held could not be restricted in other cases. *See, e.g., 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

II. PHARMACY COMPOUNDED DRUGS ARE NOT NEW DRUGS

Although Petitioners did not so argue in the Ninth Circuit, they now argue that the introduction of compounds into interstate commerce is "unlawful in all circumstances." (Pets.' Br. 18.) Whether pharmacy compounded drugs are "new drugs" and, hence, illegal to introduce into interstate commerce is the easiest issue for this Court because Petitioners represented in the Ninth Circuit that they "do not contend on appeal that the speech prohibited by section 353a concerns illegal activity or is misleading." (*See* Brief for Appellants in the Ninth Circuit Court of Appeal, at 27, n.10.) This issue has no place in this Court, as it was given token lip service in the district court, was unsupported by law and evidence, and expressly waived in the Ninth Circuit. Petitioners should be held to that waiver, as they prevented the lower court from deciding that issue. *See Lorillard Tobacco Co. v. Reilly*, 121 S. Ct. 2404, 2419 (2001) ("[W]e decline to reach an issue that was not decided below"); *United States v. United Foods, Inc.*, 121 S. Ct. 2334, 2340 (2001) (declining to reach argument not raised or addressed in the Court of Appeals and rejecting claim that argument was embraced within the question set forth in the petition for *certiorari*); *United States v. Ortiz*, 422 U.S. 891, 896 (1975).

Petitioners' original position was that Respondents' speech was inherently untruthful and misleading. (*See* Defs.' Resp. Interrog., ¶ 2.) Petitioners shifted their argument and now contend that compounds are "new drugs" pursuant to 21 U.S.C. § 321(p)(1) and, therefore, illegal to

introduce into interstate commerce without having satisfied the FDA's new drug approval process. Alas, compounding was never illegal under the FDCA and was not treated as illegal by the FDA before the CPG or in the CPG.

Petitioners' jurisdiction to address compounds as new drugs, if existent at all, would have to derive from the "new drug" definition in 21 U.S.C. § 321(p)(1). This is the foundation from which Petitioners maintain they can extract the surrender of First Amendment rights. To confer upon the FDA jurisdiction over compounds as "new drugs," there would have to be an explicit statutory grant of authority. *See, e.g., FDA v. Brown & Williamson*, 529 U.S. 120 (2000).

A. The Inapplicability Of 21 U.S.C. § 321(p)(1) And The Impossibility Of Clinical Trials For Compounds

Compounds are drugs, but not "new drugs." The determination of what is a new drug starts with an analysis of 21 U.S.C. § 321(p)(1), which requires expert evaluation for safety and effectiveness – an evaluation Petitioners represent requires in excess of $200 million. (Pets.' Br. 26.) Petitioners point out that this would be "uneconomical." (Pets.' Br. 27.) It would not only be uneconomical but impossible. To satisfy the clinical trial component of the approval process requires not only untold millions of dollars, but a statistically valid sample. *Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609 (1973), demonstrates the impossibility of applying § 321(p)(1) to compounds because of the need to present

"substantial evidence of effectiveness" for a new drug, which this Court held included "evidence consisting of adequate and well controlled investigations, including clinical investigations." *Hynson*, 412 U.S. at 614, 617. *See also United States v. 9/1 KG. Container*, 854 F.2d 173, 177 (7th Cir. 1988) (discussing veterinary drugs, the court held that a new drug " . . . requires data from large populations of animals and the application of *powerful statistical techniques.*") (emphasis added). The unavoidable dilemma, revealing these provisions incapable of application to compounded drugs, is that compounded drugs are patient-specific, typically varying in dose levels, composition, and even delivery form from patient to patient.

Petitioners' references to § 321(p)(1) always omit critical, operative words and phrases. Petitioners always only recite the "not generally recognized [ ] among experts" portion, while always omitting the "to evaluate the safety and effectiveness" portion. A key element of § 321(p)(1) is evaluation, and as Petitioners themselves report, this takes not just vast sums of money, but a vast patient database. (Pets.' Br. 26-27.) This database will never exist for compounds. Section 321(p)(1) requires that, to qualify as a new drug, the expert recognition comes after intense evaluation and, hence, must be capable of being evaluated. This "evaluation" is impossible for compounds because compounds fill extemporaneous needs not met by manufactured drugs and, consequently, would never generate a sufficiently sizeable statistical base upon which to determine safety and efficacy to the degree required for a new drug. This standard has never

been applied to compounds and, if it ever were, compounds would be eliminated, other than on a purely intrastate basis.

Petitioners' own cases establish that the new drug approval requirements cannot be applied to compounds. *See, e.g., Hynson*, 412 U.S. at 618 (a test drug must be "standardized as to identity, strength, quality, purity and dosage form to give significance to the results of the investigation") (citation omitted); *United States v. Rutherford*, 442 U.S. 544, 553 (1979) (effectiveness of new drug must be "formed on substantial evidence"); *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 652 (1973) (whether a drug is a new drug " . . . depends in part on expert knowledge and experience . . . based on controlled clinical experimentation and backed by substantial support"). These cases establish that compounds are categorically incapable of being subjected to the intense investigation required of new drugs. Compounds are not standardized, as required by *Hynson* and, by definition, do not exist in sufficient quantities for clinical trials.

B. The Effects Of 21 U.S.C. §§ 360(a)(1), 360(g)(1), And 374(a)(2)(A)

Section 321(p)(1) does not mention compounds, while other sections of Title 21 of the United States Code overwhelming support the proposition that pharmacy compounding, if compliant with these sections, is not covered by the FDCA. *See* 21 U.S.C. §§ 360(a)(1), 360(g)(1), and 374(a)(2)(A). Petitioners acknowledge that § 321(p)(1) applies only to manufacturers and distributors. Manufacturers and distributors must obtain approval, *i.e.*,

undergo the referenced evaluation, must satisfy the FDA that the drug is safe and effective, and must register, report, and be inspected by the FDA. (Pets.' Br. 2-3.)

There is no federal definition of manufacturing or compounding. (*See*, Pets.' App. 42a.) Their definitions are left exclusively to the States,[13] which definitions do not take into account volume or interstate activity. This reliance on State enforcement and adoption of State definitions is expressly incorporated into §§ 360(a)(1), 360(g)(1), and 374(a)(2)(A). Against this backdrop we address §§ 360(a)(1), 360(g)(1), and 374(a)(2)(A). Section 360(a)(1) expressly provides that the registration requirement only applies to persons or entities who distribute "from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." 21 U.S.C. § 360(a)(1).[14] This, without more, completely excludes pharmacies, because it is they which dispense to the ultimate consumer or user under State laws and § 360(a)(1).

The complete exclusion from registration found in §§ 360(a)(1) and (g)(1) is critical, as it immunizes pharmacies from the FDCA's jurisdiction if they dispense to

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[13] *See* footnotes 6 and 7, *supra*.

[14] Compare the language of § 360(a)(1), "from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user" to the language in Wis. Stat. Ann. § 450.01(7), " 'Dispense' means to deliver a prescribed drug . . . to an ultimate user . . . by or pursuant to the prescription order of a practitioner, including the compounding . . . necessary to prepare the prescribed drug . . . for delivery."

the ultimate consumer, pursuant to a physician's prescription, in conformity with State laws. Any entity that does not need to register is beyond the FDA's reach. In *FDA v. Brown & Williamson Tobacco, Corp.*, 529 U.S. 120 (2000), this Court held that, "[a] court must therefore interpret the statute as a symmetrical and coherent regulatory scheme, and fit, if possible, all parts into a harmonious whole." 529 U.S. at 133 (internal citations and quotations omitted). There is no statutory grant in the FDCA that gives the FDA jurisdiction over compounded drugs as new drugs. As this Court found in *Brown & Williamson*,

> . . . an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. And in our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.

Id. at 151 (internal citations and quotations omitted). *See also Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 652 (1973) ("[p]arties, of course, cannot confer jurisdiction; only Congress can do so").

Here, not only is there no such grant, but the FDCA explicitly excludes compounding pharmacies from registration and inspection. Once excluded from registration, compounding cannot be manufacturing since manufacturers must register. If compounds were new drugs, then the FDA would be entitled to demand registration so as to inspect the plant where the new drug is manufactured. The identical, unequivocal provisions of §§ 360(g)(1) and

374(a)(2)(A) further isolate pharmacies from the FDCA, as long as they comply with these sections.

C. Petitioners' Cases Do Not Apply

Petitioners rely on cases which do not support the proposition that pharmacy compounding in compliance with State laws is either manufacturing or creates new drugs. In *Cedars North Towers Pharmacy, Inc. v. United States*, [1978-79 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,200 (S.D. Fla. Aug. 28, 1978), Cedars was accused of packaging and shipping medications to physicians, thereby presumably taking it out of the §§ 360(a)(1), 360(g)(1), and 374(a)(2)(A) exemptions. The court in *Cedars* set out factors which, in the context of the case, it considered to be relevant in determining whether Cedars was exempt under § 360(g)(1). Not one factor related to a First Amendment restriction. Moreover, Cedars advertised products at wholesale prices, hence, not "at retail" as required by Sections 360(g)(1) and 374(a)(2)(A); and its products were also shipped exclusively to physicians for resale and not to the ultimate user. *Cedars* determined that a pharmacy is entitled to an exemption and that it needed to determine whether Cedars had "come dangerously close to crossing the line separating a pharmacy . . . from a manufacturer of drugs. . . . " *Cedars* determined that "the facts compel the conclusion that Cedars had so clearly transcended the level of normal pharmacy operation as to leave no question. . . . " *Cedars* specifically held that "the uncontested facts contained in the record required the conclusion that Cedars is compounding and selling drugs other than the

regular course of the pharmacy dispensing and selling drugs at retail."

In *Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592 (5th Cir. 1995) ("*PPCC*"), the court held that "[p]harmacies that practice traditional compounding are regulated primarily by state law and the drugs that they blend are exempt from many federal misbranding provisions." 56 F.3d at 593. *PPCC* recognized that pharmacies may not compound and sell to third parties for resale to patients without running the risk of losing their status as an excluded retail entity. *Id.* at 594. *PPCC* did not find that compounds are new drugs, but did find that the FDA's CPG was not a substantive rule. *Id.* Because it was not a substantive rule, the CPG did not impose any rights and obligations on pharmacies. *Id.* at 595. Notwithstanding Petitioners' self-serving reliance on the CPG as a historical marker, to the extent *PPCC* has any relevance, it is in the finding " . . . that traditional compounding activity is not the subject of this CPG 7132.16." *Id.* at 602.

In *United States v. Sene X Eleemosynary Corp., Inc.*, 479 F. Supp. 970 (S.D. Fla. 1979), a manufacturer was trying to parade as a pharmacy. While Sene X was compounding after the receipt of a "prescription," it was filled by one pharmacy that compounded one product. *Sene X*, 479 F. Supp. at 979. It was not extemporaneous compounding because the physician did not have any influence as to the ingredients, dosage, or delivery form. *Id.* at 978-79. In *Sene X*, the court noted that it did not address the issue whether the customary practice of pharmacy is an exemption from the new drug provisions. *Id.* at 978.

Pharmanex v. Shalala, 221 F.3d 1151 (10th Cir. 2000) dealt with manufacturers, and the FDCA's pharmacy exemption provisions were not an issue. It is clear the case related to a manufacturer which made no pretense otherwise. *Pharmanex*, 221 F.3d at 1153. In *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645 (1973), the defendant was not a pharmacy but a "drug marketer." 412 U.S. at 647. There is no mention of any pharmacy exemptions, and it would be a fair read that it involved exclusively marketers who either were or represented manufacturer(s). Similarly, *USV Pharm. Corp. v. Weinberger*, 412 U.S. 655 (1973), was brought by a "drug marketer" but the Court did not reveal whether the marketer was a manufacturer or distributor for a manufacturer. However, since there was no discussion of pharmacy compounding and a New Drug Application had issued, it could not have been a pharmacy compounding case. *Id.* at 664. In *United States v. 9/1 KG. Containers*, 854 F.2d 173 (7th Cir. 1988), the court held that § 360(g)(2) applies to all drugs made from components that may be lawfully obtained and compounded. 854 F.2d at 179. Therefore, compounding with lawfully obtained ingredients is not prohibited conduct.

D. The FDA's Historical Hands-Off Approach To Pharmacy Compounding

Petitioners have never been able to explain or reconcile how they seek to preserve the availability of compounded drugs (Pets.' Br. 19), while at the same time maintaining that before FDAMA, "the introduction of all other unapproved new drugs – was unlawful in all circumstances" (Pets.' Br. 18) or explain how restricting First Amendment rights aids this reconciliation. Petitioners

argue that their historical 59-year inaction towards pharmacy compounding is the result of a deliberate benign forbearance. A more reasoned explanation for Petitioners' 59-year inaction is their recognition that compounding, compliant with the previously cited sections, was outside its jurisdiction.

In *Rutherford*, this Court held that the FDA's implementation scheme was a salient factor in considering what the FDCA was intended to cover, and relied on the fact that the FDA had never made an exception for drugs for the terminally ill. 442 U.S. at 553. Likewise, the FDA has an uninterrupted 59 plus year history of not requiring compounds to be subjected to the new drug approval process. It is as valuable to consider the FDA's implementation history by omission as commission.

If this long-standing non-intervention was the consequence of benevolent tolerance, then the FDA is admitting that for generations it knowingly permitted illegal activity. This 59-year period is itself expert evidence that compounds are not new drugs. Petitioners admit the "FDA's longstanding enforcement policy of regulating only drug manufacturing, not ordinary pharmacy compounding." (Pets.' Br. 6.) They further concede that the FDA only took action when compounding was outside the scope of normal pharmacy practice, meaning that if compounding was within the scope of normal pharmacy practice, the FDA did not take action because it was not illegal under the FDCA, and the FDA had no jurisdiction.

Interference with the availability and sources for compounds compromises the physicians' prerogative to prescribe and treat. Compounding is a physician driven

therapy. Petitioners permit physicians to prescribe commercially available drugs for off label uses. Prescribing a compound is akin to a physician prescribing off label uses. *See Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 55 (D.D.C. 1998) ("A physician may prescribe an approved drug for any medical condition, irrespective of whether FDA has determined that the drug is safe and effective with respect to that illness.").

E. Adequacy Of Existing Regulations And Patient Protection

The absence of FDAMA does not create unreasonable risks. If risk was a legitimate concern, then, as Judge Ezra pointed out in his Opinion, the FDA could entirely prohibit compounding. (Pets.' App. 34a.) Further, if safety and efficacy were indeed meaningful concerns, then First Amendment restrictions are meaningless, as they afford no protection.

The patient's protections include the physician's diagnosis and determination of appropriate therapy, issuance of a prescription, evaluation of that prescription, which includes application of her training and judgment as a licensed professional, and collaboration between them. In addition, the pharmacy codes and enforcement activities of all the States in which the pharmacies are located, and 26 States into which they dispense, provide added protection. It is further telling that notwithstanding their penchant for anecdotal "evidence," Petitioners offer no modern examples of problems with compounds. Petitioners also never reference the FDA approved drugs which proved unsafe after entering the market.

It is conceivable that some time, some pharmacy will operate outside the exclusions set up in the FDCA and beyond the scope of State laws. On that day, the FDA and State authorities will be able to take enforcement action against that pharmacy which took itself outside the exemptions. However, this enforcement goal and scheme is not advanced by the First Amendment restrictions.

It is irreconcilable for Petitioners to maintain that the interstate dispensing of compounds is illegal under all circumstances after Petitioners and Congress have routinely, historically, and consistently permitted, tolerated, praised, protected and endorsed compounding in statutes and in all briefs in this case.

III. PETITIONERS CANNOT CONDITION EXEMPTION FROM THE FDA'S NEW DRUG APPROVAL PROCESS ON RELINQUISHMENT OF FIRST AMENDMENT RIGHTS

Respondents maintain compounds are not new drugs. In the event this Court disagrees with that contention, Respondents further maintain an exemption cannot be conditioned on restrictions of First Amendment rights. Petitioners assert that FDAMA's exemption of compounds from the FDCA's new drug approval requirements is contingent upon pharmacies' surrender of their First Amendment right to advertise and solicit. (Pets.' Br. 7-8, 18-19, 42-43.) Petitioners claim that the "government may condition a benefit on their relinquishment of a constitutional right if waiver of the right is reasonably related to the benefit." (Pets.' Br. 42-43, *citing Dolan v. City of Tigard*, 512 U.S. 374, 385, 391 (1994) and *Pickering v.*

Board of Educ., 391 U.S. 563, 568 (1968).) Petitioners did not raise this argument anywhere below and, hence, this Court should not reach that issue. *See, e.g., Lorillard Tobacco Co. v. Reilly*, 121 S. Ct. 2404, 2420 (2001) ("We decline to reach an issue that was not decided below."); *United States v. United Foods, Inc.*, 121 S. Ct. 2334, 2340 (2001); *United States v. Ortiz*, 422 U.S. 891, 896 (1975).

The claim is based on false assumption as well as a syllogism previously rejected by this Court. Petitioners' purported "exemption" of compounds is illusory. As discussed above (Part II, *supra*), by statute and FDA conduct, compounds are not and have never been treated as "new drugs." Petitioners have attempted to create a hollow bargain – that Respondents must forego their First Amendment rights to advertise and solicit in exchange for an exemption from regulation that is inapplicable in the first place. To dispense compounds, Respondents need not relinquish their First Amendment rights.

If, hypothetically, the Court were to find that compounds are new drugs, Petitioners nonetheless cannot condition an exemption upon Respondents' relinquishment of First Amendment rights. *See 44 Liquormart Inc. v. Rhode Island*, 517 U.S. 484, 513 (1996) (Stevens, J., joined by Kennedy, J., Thomas, J., and Ginsburg, J.) ("it does not follow that conferral of the benefit may be conditioned on the surrender of a constitutional right"). Although the Court tolerated such a scheme in *Posadas de Puerto Rico Associates v. Tourism Co. of P.R.*, 478 U.S. 328 (1986), the Court has since rejected Petitioners' position as a false syllogism. *See 44 Liquormart*, 517 U.S. at 510-14. *44 Liquormart* distinguished and disavowed that "greater-includes-the-lesser" argument because "it is inconsistent with both

logic and well-settled doctrine." *44 Liquormart*, 517 U.S. at 514. In *44 Liquormart*, the Court rejected the proposition that the power to regulate commercial activity is greater than the power to ban truthful, non-misleading commercial speech. *Id.* at 511-12 ("The text of the First Amendment makes clear that the Constitution presumes that attempts to regulate speech are more dangerous than attempts to regulate conduct. . . . As a result, the First Amendment directs that government may not suppress speech as easily as it may suppress conduct. . . . ").

Recognizing that this Court rejected its argument in *44 Liquormart*, Petitioners rework their words and try again. Instead of asserting that the greater power to regulate conduct can justify restricting speech related to that conduct, Petitioners argue in this case that the speech restrictions are a condition on an exemption from regulating the conduct. This gets Petitioners no farther. FDAMA's restriction on advertisement and solicitation as a condition upon the alleged "exemption" violates the First Amendment.

The cases upon which Petitioners rely in support of the newly minted "relinquishment theory," *Dolan v. City of Tigard*, 512 U.S. 374 (1994) and *Pickering v. Board of Educ.*, 391 U.S. 563 (1968), do not support Petitioners' claim. *Dolan* raised no First Amendment issues, but was a Fifth Amendment case that held that the government may not require a person to give up the right to receive just compensation when property is taken for public use. 512 U.S. at 385. In *Pickering*, this Court held that "the theory that public employment which may be denied altogether may be subjected to any conditions, regardless of how unreasonable has been uniformly rejected." 391 U.S. at

568, *quoting* citing *Keyinshan v. Board of Regents*, 385 U.S. 589, 605-606 (1967). These cases do not save Section 353a.

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the judgment of the Ninth Circuit Court of Appeals be affirmed.

Respectfully Submitted,

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